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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/954,988 | 09/15/2001 | Donald W. Hansen JR. | 3366/1 US | 7678 |

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER

ZUCKER, PAUL A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1621

DATE MAILED: 10/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/954,988

Applicant(s)

HANSEN ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-203 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 202 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 9. Claims 1-12, 19-23, 31-40, 50, 58, 66- 79, 89, 97-107, 114-118, 125, 133 -146, 153-156, 164-174, 181-184, 192, 200, 201 and 203 .

Continuation of Disposition of Claims: Claims objected to are 13-18, 24-30, 41-49, 51-57, 59-65, 80-88, 90-96, 108-113, 119-124, 126-132, 147-152, 157-163, 175-180, 185-191 and 193-199.

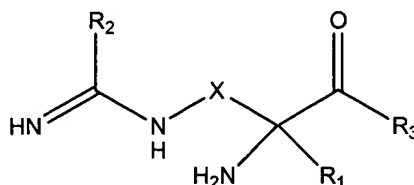
DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 28 June 2003 in Paper No 10.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Claims 1-203 remain outstanding.
4. The rejection for Double Patenting set forth in paragraph 12 of the previous Office Action in Paper No 4 is withdrawn in response to Applicant's execution of a proper terminal disclaimer.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-12, 19-23, 31-40, 50, 58, 66- 79, 89, 97-107, 114-118, 125,133 –146, 153-156, 164-174, 181-184, 192, 200, 201 and 203 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al (WO 95/25717-A1 10-1995). Currie generically teaches (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



Where R₃ may be hydroxyl, R₂ may be methyl and R₁ may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl and lower alkynyl, where lower denotes 1-6

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carbons. All of the compounds Currie exemplifies (See page 23, line 12 –page 24, line 10, for example) have the substitution pattern corresponding to the instant variables R_1 and R_2 where R_1 and $R_2 = CH_3$. Thus the only selection required is to select an alkylene group for X. Currie provides further guidance (Page 29, lines 27-31) for such selection in claim 4 in which the suggested alkylene subgenus is further narrowed.

Thus the instantly claimed compounds would have been obvious to one of ordinary skill in the art. One of ordinary skill would have been motivated to make the compounds by Currie's teaching that they have activity as nitric oxide synthase inhibitors. Currie provides clear guidance for the selection of the small subgenus of his genus that corresponds to the instantly claimed compounds. There would therefore have been a reasonable expectation for success.

Examiners response to Applicants' Remarks with Regard to This Rejection

6. Applicants have presented several arguments with regard to this rejection. The Examiner responds to these below:

- a. Applicants' argue that Currie does not define the term "alkylene" and that the preferred interpretation of "alkylene" should be based on:
 - i. Standard usage of the term as evidenced by the Manual of Classification;
 - ii. The disclosure of Currie as a whole, which does not exemplify an olefinic chain for the variable group X.

The Examiner agrees that Applicants' arguments have some merit with regard to the indicated citation but argues that, in light of Currie's disclosure as a whole, these arguments do not obviate Currie's teaching of an olefinic chain for the variable group X. In Claim 1 of Currie (Page 27, line 12), for example, Currie clearly teaches X as lower akenyl. Currie further limits (Page 7, lines 19-20) this to "lower alkenyl of 1 to 6 carbon atoms". Thus, regardless of the disputed interpretation of the term "alkylene", Currie provides clear guidance for selection of an olefinic chain for X.

- b. Applicants' further argue that a very large group of compounds is obtained if further substitution of the olefinic chain is allowed. The Examiner agrees with Applicants but points out that further substitution is not at issue in this rejection which is limited to those claims which are drawn to compounds having an unsubstituted olefinic chain of 4 carbon atoms (within the preferred subgenus of Currie of 1-6 atoms) as is instantly claimed. This group of all possible positional and *cis-trans* isomers consists of six compounds. This, taken into consideration with the fact that all of the compounds exemplified by Currie have the instant selection of variable groups other than X, renders the instantly claimed unsubstituted olefins obvious over the teachings of Currie.

Applicant's arguments filed 28 June 2003 have been fully considered but they are not persuasive for the reasons indicated above.

Claim Objections

7. Claims 13-18, 24-30,41-49, 51-57, 59-65, 80-88, 90-96, 108-113,119-124, 126-132, 147-152, 157-163, 175-180, 185-191, 193-199 are finally objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

8. Claims 13-18, 24-30,41-49, 51-57, 59-65, 80-88, 90-96, 108-113,119-124, 126-132, 147-152, 157-163, 175-180, 185-191, 193-199 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record, Currie et al (WO 95/25717-A1 10-1995), teaches (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I) that encompasses the instantly claimed compounds. Currie, however, does not provide sufficient direction to one of ordinary skill in the art to allow selection of the instantly claimed more highly substituted alkeneyl chains. Claims 13-18, 24-30,41-49, 51-57, 59-65, 80-88, 90-96, 108-113,119-124, 126-132, 147-152, 157-163, 175-180, 185-191, 193-199 are therefore patentable over the teachings of Currie.

Conclusion

9. Claims 1-12, 19-23, 31-40, 50, 58, 66- 79, 89, 97-107, 114-118, 125,133 –146, 153-156, 164-174, 181-184, 192, 200, 201 and 203 are finally rejected. Claims 13-18, 24-30,41-49, 51-57, 59-65, 80-88, 90-96, 108-113,119-124, 126-132, 147-152, 157-163, 175-180, 185-191, 193-199 are finally objected to. Claim 202 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker, Ph.D.
Patent Examiner
Technology Center 1600



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